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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,146	03/17/2004	Nancy Jean Britten	01559.US1	5036
25533 7590 01/10/2008 PHARMACIA & UPJOHN 7000 Portage Road KZO-300-104 KALAMAZOO, MI 49001				
			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,146

Applicant(s)

BRITTEN ET AL.

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/7/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the group II invention, claims 25-58 in the reply filed on October 11, 2007 is acknowledged.

Claims 16-24 and 59-61 have been cancelled.

Claims 25-58 are presented for examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-70 of copending Application No. 10/795191. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the inclusion of an antimicrobial agent in the conflicting claims. For instance, conflicting claim 30 requires an antimicrobial agent in addition to an anti-inflammatory agent, analgesics, antipyretics, in combination with a vehicle that includes an amphipathic oil, microcrystalline wax and a non-aqueous carrier. None of the instant claims recites that specific combination, but instant claims 25-58 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper

subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 25-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-30 and 32-34 of copending Application No. 10/393,098. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present invention is drawn to a pharmaceutical composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier, with anti-inflammatory agents. The claims of Application No. 10/393,098 are drawn to a pharmaceutical composition comprised of an antibacterial agent and a COX-2 inhibitor in a non-aqueous vehicle comprised of vegetable oil. Because the present application is drawn to active agents being an anti-inflammatory agent, it would be obvious to employ the COX-2 inhibitor taught by Application No. 10/393,098 as the anti-inflammatory agent of the present claims, because it is a well-known anti-inflammatory agent that would effectively treat mastitis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30, 34-36, 42-45, 52, 59-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59-60 of copending Application No. 10/903,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present invention is drawn to a pharmaceutical composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier, with an anti-inflammatory agent. The claims of Application No. 10/903,662 are drawn to a pharmaceutical composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier, with an antibacterial agent and a second agent selected from anti-inflammatory agents and analgesics. The claims of Application No. 10/903,662 are obvious over the present invention because they are drawn to active agents being an antibacterial agent and a second agent selected from anti-inflammatory agents and analgesics, of which overlap the claims of the present invention which can comprise an antibacterial agent and an anti-inflammatory agent or an analgesic.

\This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 30-32, 42-67 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28, 31-34 and 37-61 of copending Application No. 10/909,050. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the present invention is drawn to a pharmaceutical composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier, with an anti-inflammatory agent. The claims of Application No. 10/909,050 are drawn to a pharmaceutical composition comprising a vehicle that comprises an amphipathic oil that is water dispersible and ethanol insoluble, microcrystalline wax, and a non-aqueous carrier with an anti-inflammatory agent. Because the present claims are drawn to the composition comprising an anti-inflammatory agent and the claims of Application 10/909,050 are drawn to the active agent being an anti-inflammatory agent, in the same carrier, it would be obvious because both applications are compositions that are useful for the same purpose.

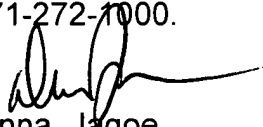
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Donna Jagoe
Patent Examiner
Art Unit 1614

January 6, 2007